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EXAMINER	
SIMS, JASON M	
ART UNIT	**PAPER NUMBER**
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/686,263	SYROID ET AL.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 4/19/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 4/19/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 6-49 are the current claims hereby under examination.

Information Disclosure Statement

Applicant has requested that the office consider and make of record a supplemental Information Disclosure Statement filed on March 29, 2006. However, the office, at least the examiner, does not have any such supplemental Information Disclosure Statement filed March 29, 2006 and therefore cannot consider or make it of record. The latest Information Disclosure Statement the office has of record was filed March 24, 2006 and has already been considered and made of record.

Claim Rejections - 35 USC § 112

Applicant's arguments, filed 4/19/2007, with respect to the rejection of claims 6-49 under 35 USC 112 first paragraph as lacking written description have been fully considered and are persuasive because applicant has sufficiently pointed to the specification where support can be found. Therefore the rejection of claims 6-49 under 35 USC 112 first paragraph as lacking written description has been withdrawn.

Applicant's arguments, filed 4/19/2007, with respect to the rejection of claim 35 under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant amendments to the claim. Therefore the rejection of claim 35 under 35 USC 112 second paragraph has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's arguments filed 4/19/2007 have been fully considered but they are not persuasive.

Applicant alleges that neither Howson nor Johnson taken alone or together teaches or suggests each and every element of any of these claims and reiterates to what independent claim 6 is directed. Applicant specifically states both Howson and Johnson both lack any teaching or suggestion of a drug display monitor that is configured to depict, in real time, a probability of effectiveness of at least one drug.

Applicant's allegations are not found persuasive. Applicant's claimed invention is drawn to a display monitor configured to depict, in real time, a probability of effectiveness of at least one drug. Howson et al. in the abstract, discloses a programmable element of the invention that ensures an effective application of a therapeutic agent wherein the programmable element effects the delivery of therapeutic agents. Additionally, Howson et al. discloses said programmable element to be customized for a particular patient during each minute of each day, which inherently teaches a patient being monitored in real time. Furthermore, Howson et al. at col. 7, lines 4-57, discloses using patient and drug databases, protocols, graphics, and

pharmacokinetic algorithms to determine accepted drug dosage ranges and safe and effective dosages, which is all done in real time. Howson et al. discloses how the logic cartridge contains sections of configurable logic suitably different from the base configurations so as to allow small changes in effective dosage rates from the base program and data, from pharmacokinetic, pharmacodynamic, or dose-response models, which use substance concentrations to aid programming of the delivery profile and/or adjust dosages, may be communicated to the delivery unit's logic cartridge to take effect. Moreover, Howson et al. at col. 9, lines 26-40, discloses the control unit monitoring in real time, patient data, and how the control unit may comprise a display unit or display window, which gives a visual indication of the therapeutic agent then in each syringe, which is the result of delivery profiles, which determine in real time effective dosage rates, which inherently is displaying a probability of effectiveness based on real time data. In addition, Johnson et al. at the abstract, discloses a PK model controlling drug delivery, which uses drug data to determine effective dosage rates, present, and future effect compartment drug concentrations and displays the information to a user on an electroluminescent display, which reads on a display monitor configured to depict in real time a probability of effectiveness of at least one drug.

Applicant further alleges that neither Howson nor Johnson includes any teaching or suggestion of a system that includes a normalizer, but are limited to a system that are configured to model and, optionally, display raw drug concentration data.

Applicant's allegations are not found persuasive because it is an inherent property of using pharmacokinetic modeling that normalization of data occurs, which in both Howson and Johnson both use PK models for determining effective drug delivery dosages, which inherently reads on a system that includes a normalizer.

Applicant further alleges that neither Howson nor Johnson suggest or teach a system that displays a three-dimensional representation of a probability of effectiveness of at least one drug.

Applicant's allegations are not found persuasive as Howson et al. discloses, as discussed above, a display that depicts syringes filled with a determined, based on the pharmacokinetic modeling, effective dosage, which reads on a three-dimensional representation of a probability of effectiveness of at least one drug.

Applicant further alleges that the teachings of Howson, Johnson, and Teeple fail to teach or suggest every limitation of claims 14, 22-40, and 44-49. Applicant reiterates the limitations of independent claim 14 and then specifically points to the failings of the references to teach the appropriate display.

Applicant's allegations are not found persuasive as Howson et al. at col. 9, lines 26-40, discloses the control unit monitoring in real time, patient data, and how the control unit may comprise a display unit or display window, which gives a visual indication of the therapeutic agent then in each syringe, which is the result of delivery profiles, which determine in real time effective dosage rates, which inherently is displaying a probability of effectiveness based on real time data. In addition, Johnson et al. at the abstract, discloses a PK model controlling drug delivery, which uses drug data

to determine effective dosage rates, present, and future effect compartment drug concentrations and displays the information to a user on an electroluminescent display, which reads on a display monitor configured to depict in real time a probability of effectiveness of at least one drug. Furthermore, Teeple at col. 7, lines 57-67, col. 8, lines 1-8 teaches the customized administration of anesthetic drugs to a patient, which depend on the individual patient and how calculations should be compared to standardized dosage rates, which reads on administering drugs to give a probability of effectiveness. Moreover, Teeple teaches anesthetic drugs that cause patients to loose consciousness. Additionally, Teeple, at col. 8, lines 55-64 discusses a monitor that displays the input and output of the calculations, which results in a customized dosage rate, which further reads on a display configured to show a probability of effectiveness of at least one drug causing a patient to loose consciousness as described previously.

Applicant further alleges that claims 27-30 is allowable because the references fail to teach a monitor displaying a probability of effectiveness as a percent likelihood that at least one drug has a desired effect whereby the effectiveness is a ninety five percent probability.

Applicant's allegations are not found persuasive as Johnson at col. 10-15 teaches the method steps involved in determining a probability of effectiveness, which inherently are able to predict a ninety five percent probability of an effect drug compartment concentration.

Applicant alleges claims 31, 35, and 46 are found allowable for reasons not found persuasive as have been discussed above, such as Teeple teaches a system for

administering a calculated dosage rate for anesthetic drugs, which includes at least one or more.

Applicant makes repetitive argumetns as to why the cited references fail to teach or suggest all of the limitations of claims 35, 36-40, and 47-49, such as they fail to teach or suggest a display configured to depict at least one concentration at which the at least one drug will have a desired effect or at least two anesthetic agents to cause a subject to lose consciousness, which have all been discussed in the above instant office action.

Therefore, because of the above stated reasons the rejection in the Non-Final Office Action mailed 12/14/2006 is being maintained.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 8-10, 12-13, 15, 20-21, and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson U.S. Patent Number 5,088,981 in view of Johnson et al U.S. Patent Number 5,522,798.

The claims are drawn to a system for data representation comprising a drug delivery system, a data stream device and a drug display monitor.

Howson et a1 ('981) discloses a system for data representation comprising a drug delivery system (52, 54) a data stream device (50) in communication with the drug delivery device system (52, 54) and a drug delivery display monitor (28), in communication with a data stream device (50), see figures 1 and 2. Furthermore, Howson et al ('981) discloses that the drug delivery system comprises a simulator, which simulates bolus, infusion and anesthetic drug administration (col. 4 line 3). Moreover, Howson et al ('981) discloses a drug display monitor (28) comprising a data decoder (20) receiving data from the data stream device (50); a dosage calculator (32) receiving decoded data from the data decoder; a drug modeler (26) and normalizer (24) receiving calculated data from the data decoder; a storage device (16), receiving drug and dosage data from the drug modeler and normalizer; and a display generator (28), wherein the display generator produces a display of more than one drug dosages, drug name, past, present and predicted drug site concentration and effect site concentration in three-dimensional form and a system for data representation comprising a processor (16), computing drug models, producing an internal representation of drug display data and decoding a data stream; a memory unit in communication with the processor; a graphics adapter (24c) in communication with the processor and a display monitor in

communication with the graphics adapter, see figures 1 and 2 and col. 13, 14 and 15. Additionally, Howson et al ('981), at col. 7, lines 5-65 discloses how the drug concentrations and dosages are calculated based on information obtained from databases, in real time, that include patient history information, drug database information, and pharmacokinetic algorithms to provide accepted drug dosage ranges, drug to drug interaction, and mathematical support for dose-response information, which represents a monitor that is configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject. Moreover, a monitor that is configured to depict present and future drug dosages, which uses databases and algorithms to aid in calculating a proper drug dosage, is depicting a probability of effectiveness in the form of a drug dosage. The calculated drug dosage for a particular patient is based on that patient's history information, which may include past treatment history in coordination with drug database information and pharmacokinetic algorithms, and the result is a proper drug dosage to be delivered to cause a particular drug concentration in the patient, which has a particular real-time probability of effectiveness based on current and past available data. Howson et al ('981) further discusses at col. 10, lines 55-67 and col. 12, lines 20-66, the design of profiles for patient drug delivery and how these profiles, when complete, have the computer validate the profile to ensure that arithmetic, procedural, or conceptual errors have not been made, and the profile can even be simulated or tested in software prior to the instructions being executed, which reads on the amended phrase "probability of

effectiveness." Howson et al ('981), at col. 15 and 16, further discloses a system that can be used to manage each of the infused drugs and other drugs as well and the user can ask the computer to use pharmacokinetic algorithms to help derive optimum profiles for the patient. The system is a comprehensive medication management system, which is configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject.

Howson et al fails to explicitly disclose that the drug monitor is configured to depict past, predicted and real-time probability of effectiveness.

Johnson et al discloses a similar device, which graphically depicts past, predicted, and real-time drug concentrations (col. 17. line 44 and col. 12 line 9), which is an obvious form of a past, predicted, and real-time probability of effectiveness. Johnson et al., at col. 7, discloses how these concentrations are calculated based on drug data that may be uploaded, patient history data, or PK model data, all of which are used to calculate and deliver a particular drug concentration. The data that the calculations are dependent are based on correlations between concentrations and effectiveness. A patient's history data helps establish a record of what concentrations had what effects on a patient and enable a prediction of a concentration and an expected probability of effectiveness to be calculated based on this data, drug data, or PK model data. In other words, a display of a past, predicted, or real-time concentration of a drug, is a display of a past, predicted, or real-time probability of effectiveness since the calculations are based on known data that correlates concentrations, time, and effectiveness.

Therefore, a drug monitor that graphically depicts past, predicted, and real-time drug concentrations are necessarily configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject. Moreover, Johnson et al teaches that the display monitor is configured to depict a percent likelihood that the at least one drug has a desired effect based on results from a predefined population that is at least ninety-five percent of the population and wherein a plurality of inputs includes the height and weight of the subject (see col. 15 line 60).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Howson et al by incorporating the graphical drug concentration display of the type taught by Johnson et al in order to give the physician information in evaluating the need for changes in the desired drug concentration set point (col. 17 line 49).

Claims 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al ('981) in view of Teeple Jr. U.S. Patent Number 5,925,014.

The claims are drawn to a system for data representation comprising a drug delivery system, a data stream device and a drug display monitor, wherein the drug delivery system comprises an infusion pump, a gas administration machine, and one or more bolus injection apparatus and the simulator simulates anesthetic drugs.

Howson et al ('981) discloses the drug delivery system as described above in reference to claim 6 and further comprising an infusion pump (14 see col. 10 line 13).

Howson et al ('981) fails to disclose an anesthetic administration machine and one or more bar coded syringes. Teeple Jr. discloses an anesthetic administration machine (30 see figure 3); and one or more bar coded syringes (31-33 see figure 3). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the drug delivery system of Howson et at ('981) by incorporating anesthesia administration and bar coded syringes as taught by Teeple Jr. ('014) in order to insure that the proper drug mix is achieved, reducing if not eliminating the possibility for human error (Teeple Jr. col. 4 line 67).

Claims 14, 22-34, 35-40, and 44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al in view of Johnson et al and further in view of Teeple Jr. Howson and Johnson disclose the device as described above, but fail to explicitly disclose that the components are sedative, neuromuscular blocker, anesthetic agents, and analgesic agents (col. 10 line 27 and col. 1 line 19) and that the display monitor configured to depict a present probability of effectiveness is one wherein the effectiveness of at least one drug in a subject at: causing the subject to lose consciousness; eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain; or causing a measurable level of muscle relaxation. Anesthetic agents, which would be administered for purposes of anesthesia represent a probabililty of effectiveness on a subject at: causing the subject to lose conciousnes and eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain. Anesthesia, as evidenced by google, is either local, general, or regional and the desired effects of

anesthetic agents at the local, general, or regional level is evidenced by the definitions of general, local, and regional anesthesia; such as "General anesthesia puts the patient to sleep," (i.e. loss of consciousness) "local anesthesia numbs a specific body part. Regional anesthesia, such as spinal anesthesia and epidural anesthesia, numbs the nerves that conduct sensation to a circumscribed body area." Therefore, a system that comprises a display monitor configured to depict drug concentrations, which represent a probability of effectiveness, where the drugs are anesthetic agents, represents drug concentrations with a probability of effectiveness where that effectiveness includes a subject at: causing the subject to lose conciousnes and eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain.

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device Howson in view of Johnson by adding the sedative, analgesic and neuromuscular agents as taught by Teeple Jr. in order to make a more effective drug delivery system.

Double Patenting-Maintained-Maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 6-11, 15, and 19 of copending Application No. 10/269422 in view of Johnson et al (US P/N 5,522,798). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Howson et al fails to explicitly disclose that the drug monitor is configured to depict past, predicted and real-time probabilities of effectiveness. Johnson et al

discloses a similar device, which does graphically depict past, predicted and real-time drug concentrations (col. 17. line 44 and col. 12 line 9), which read on past, predicted and real-time probabilities of effectiveness. Johnson et al., at col. 7, discloses how these concentrations are calculated based on drug data that may be uploaded, patient history data, or PK model data, all of which are used to calculate and deliver a particular drug concentration. The data that the calculations are dependent are based on correlations between concentrations and effectiveness. A patient's history data helps establish a record of what concentrations had what effects on a patient and enable a prediction of a concentration and an expected probability of effectiveness to be calculated based on this data, drug data, or PK model data. In other words, a display of a past, predicted, or real-time concentration of a drug, is a display of a past, predicted, or real-time probability of effectiveness since the calculations are based on known data that correlates concentrations, time, and effectiveness. Therefore, a drug monitor that graphically depicts past, predicted, and real-time drug concentrations are necessarily configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject. Moreover, Johnson et al teaches that the display monitor is configured to depict a percent likelihood that the at least one drug has a desired effect based on results from a predefined population that is at least ninety-five percent of the population and wherein a plurality o inputs includes the height and weight of the subject (see col. 15 line 60).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Howson et al by incorporating the graphical drug concentration display of the type taught by Johnson et al in order to give the physician information in evaluating the need for changes in the desired drug concentration set point for a more accurate probability of effectiveness(col. 17 line 49).

This is a provisional obviousness-type double patenting rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla can be reached via telephone (571)-272-0735.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

Primary Patent Examiner
7/9/07